

REMARKS

In the Drawings

The drawing is objected to for failing to comply with 37 CFR 1.84(p)(5) because it contains the reference character 1/1 and is improperly referred to in the specification as “the sole accompanying drawing figure.” In response to this objection, Applicant submits a corrected replacement-drawing sheet in compliance with 37 CFR 1.84(c). The only amendment to the drawing is the addition of the reference character “FIG. 1.” Applicant hereby requests approval of this change.

Rejections under 35 USC 112, second paragraph

Claims 1-7 have been rejected under 35 USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. More specifically, the term “extract” as recited in Claims 1-3 and 7 is considered vague, and the term thus renders indefinite any of the claims containing the term. More specifically the Patent Office states:

An “extract” is necessarily a product-by-process because the composition of the “extract” is only defined by the process of its preparation...Since any given biological source contains thousands of extractable compounds, each with its own particular extraction properties, the nature of the resulting “extract” will depend on the conditions of the extraction and the solvent used...It is well accepted in the natural products and herbal art, that extraction of a biological source with one of various distinct solvents has a profound impact on the final product with respect to the presence, amounts, and/or ratios of active ingredients obtained, and, thus on the ability of the “extract” to provide the desired functional effect(s) claimed and/or disclosed.

In response, Applicant has amended Claims 1 and 3 to more clearly define the term “extract.” More specifically, Claim 1 been amended to define the extract as a product by process claim to more distinctly define Applicant’s invention. Claim 1 as amended recites that the extract is made by a process comprising combining dried *Scutellaria lateriflora* L. plant material with a solvent to form an aqueous solution. Claim 1 as amended further recites that the extract is processed by heating said solution to at least 70°C. The extract, as claimed, is then obtained by separating solid material from said solution after a predetermined period, whereby said

Amendments to the Drawings

The attached sheet of drawings includes changes to Fig. 1. This sheet, which includes Fig. 1, replaces the original sheet including Fig. 1.

Attachment: Replacement Sheet

extract has a content of flavonoids, calculated as the sum of baicalin, scutellarin, dihydrobaicalin, ikonnikoside 1, lateriflorin, baicalein, lateriflorein and wogonin, of at least 18% by weight. Claim 3 has been similarly amended to more clearly recite the process of the invention. Claim 3, as amended, recites that the solution for the process of the invention is an aqueous solution. Furthermore, the additional limitation of heating the solution to at least 70°C has been added to Claim 3. Support for the heating of an aqueous extract containing solution to at least 70°C in the claimed process, and an extract claimed by the process thereof, may be found in paragraph 16 of the instant specification as filed (paragraph 18 of the published application). New Claim 21 has been added, which is directed to a process for making an extract of *Scutellaria lateriflora* L. using an alcohol containing solution. New Claim 20 has been added, which is directed to the extract made by this process thereof. Support for the use of aqueous and alcohol solutions in the claimed process may be found throughout Examples 1 and 2 and in original Claims 4, 5, and 18. Applicant respectfully submits that the aforementioned amendments obviate this rejection of Claims 1-3 and 7. Applicant further submits that the amendments and addition of new claims does not add new matter.

Claims 1-3 have been further rejected under 35 USC 112, second paragraph because the percentage amounts of the ingredients are not set forth in terms of "by weight" of the total composition, thereby further rendering these claims indefinite. In response, Applicant respectfully submits that the amendments specified above obviate this rejection of said claims. The parameters of the process of the claimed invention have been more specifically defined by such amendments, thus defining the claimed process and extract made by the process thereof. In the rejected claims as amended, the composition of the extract is explicitly defined by the process by which the product is made, rather than the percentage "by weight" of total composition values. The composition of the extract in terms of its "by weight" of total composition is inherent in the claimed process and the claimed product made by the process thereof. Therefore, Applicant respectfully submits that the process of the claims as amended defines the metes and bounds of the extract recited in said claims, and therefore the "by weight" of total composition for each component within the extract need not be explicitly stated for the claims to be rendered definite.

Claim 6 has been further rejected under 35 USC 112, second paragraph for lack of proper antecedent basis for the term "solution." In response, Claim 6 has been amended to recite "...said solution..." thereby obviating the rejection of this claim.

Rejections under 35 USC 102

Claims 1 and 2 have been rejected under 35 USC 102(b) as being anticipated by Millspaugh and Nishikawa et al. More specifically, the Patent Office states:

...Millspaugh teaches an evaporated, powdered tincture of *Scutellaria Laterifolia* made with 76 per cent alcohol, after dilution with water several times its bulk of water... Nishikawa teaches an extract of *Scutellaria Laterifloria* comprising concentrations of flavenoids, such as acetoside (1), baicalin (2), wogonin 7-glucuronide (3), baicalein (4), wogonin (5), skullcapflavone I (6), skullcapflavone II (7), and chrysin (8)...The plant source material and the ingredients used in the making of the plant extracts taught by Millspaugh and Nishikawa are the same as instantly disclosed by Applicant...

Applicant respectfully traverses this rejection. Applicant respectfully submits that the plant source material used in the making of the plant extracts taught by both Millspaugh and Nishikawa are different than those used to arrive at the extract of Claims 1 and 2. Because the source material is vastly different, an extract made from the source material in Nishikawa or Millspaugh is vastly different from the extract of Applicant's rejected claims. As stated in Example 2 of the instant specification, Applicant's invention is based in part on the finding that dried *S. lateriflora* extracts result in better flavonoid extraction and more stable extracts than fresh extracts. The source material in Applicant's Claims 1 and 2, as amended, is therefore dried plant material. In contrast, Nishikawa teaches use of *S. lateriflora* tissue culture cells as source material. One of skill in the art would expect the composition of an extract made from dried plant material to be vastly different from that obtained from cell culture experiments. Indeed, the composition as reported by Nishikawa is very different from the extract of Applicant's rejected claims. Nishikawa reports that the composition obtained from *S. lateriflora* in tissue culture contain hardly a detectable amount of baicalin, while at the same time reporting that the major phenolics consist essentially of baicalein and wogonin (see Figure 1 of Nishikawa). In strict contrast, an extract of Applicant's Claims 1 and 2 contain predominantly baicalin, dihydrobaicalin, scutellarin, ikonnikoside I, lateriflorin and oroxylin A-7-O-glucuronide,

with only very small amounts of baicalein and wogonin. Thus, the composition of the Applicant's extract from dried plant material is indeed very different from that obtained from tissue culture cells, as taught by Nishikawa. Applicant respectfully submits that the claimed invention is free of the cited art.

Similarly, Millspaugh teaches use of fresh *S. lateriflora* plant as the source material. In fresh material, phenolics decompose quickly. As stated above and in Example 2 of the instant specification, Applicant's invention is based in part on the finding that dried *S. lateriflora* extracts result in better flavonoid extraction and more stable extracts than fresh extracts. An extract made from dried *S. lateriflora* plant source material of Applicant's Claims 1 and 2 is not taught by Millspaugh. Even though Millspaugh does not teach the phenolic composition of the disclosed powdered tincture of *Scutellaria Laterifolia* made with 76 per cent alcohol, such extract is inherently different from that claimed by Applicant. Applicant respectfully submits that the claimed invention is thus free of the cited art.

Rejections under 35 USC 102 / 35 USC 103

Claims 1-7 have been further rejected under 35 USC 103(a) as obvious over Millspaugh and Nishikawa in view of Sheu et al., Wang et al., and Charaux et al. More specifically, the Patent Office states:

...the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced compositions (of Millspaugh and Nishikawa) are likely to inherently possess the same characteristics of the claimed composition particularly in view of the similar characteristics which they have been shown to share, e.g., the plant source, the solvents, the process steps of extraction...

Applicant respectfully traverses this rejection. As stated above, Applicant's invention is based in part on the finding that dried *S. lateriflora* extracts result in better flavonoid extraction and more stable extracts than fresh extracts. The source material in Applicant's Claims 1 and 2, as amended, is therefore dried plant material. In contrast, Nishikawa, teaches use of *S. lateriflora* tissue culture cells as source material, and Millspaugh teaches use of fresh *S. lateriflora* plant as the source material. For the reasons explicitly set forth above for 35 USC 102, the extract of

Applicant's claims is distinct from the compositions taught by Nishikawa and/or Millspaugh. In support of its rejection, the Patent Office further states:

...It would have been obvious to one of ordinary skill in the art to obtain an extract of *Scutellaria lateriflora* L. having a content of flavenoids by using the instantly claimed ingredients, solvents, process steps and experimental parameters because...at the time the invention was made it was known in the art of herbal extraction to use the instantly claimed process steps to obtain flavenoids from dried plant material of a species of *Scutellaria*, as evidenced by the teachings of Sheu, Wang, and Charaux...

In response, Applicant respectfully traverses this rejection. Again, as stated above, Applicant's invention is based in part on the finding that dried *S. lateriflora* extracts result in better flavonoid extraction and more stable extracts than fresh extracts. Applicant respectfully submits that the source material of the claimed invention, as defined in the claimed process of the instant claims, is different than any of the source materials taught by the cited references. As stated above, Millspaugh teaches use of fresh *S. lateriflora* plant as the source material, and Nishikawa teaches use of *S. lateriflora* tissue culture cells as source material. Like Millspaugh, Charaux teaches use of fresh *Scutellaria* plant as the source material. Sheu et al. and Wang, as characterized by the Patent Office, teach extracts from species of *Scutellaria* not claimed by Applicant. None of the cited references thus teach use of the same source material as that of Applicant's claims—dried plant material from *Scutellaria lateriflora* L.—and the cited combination of references does not cure this deficiency. One of skill in the art would expect extracts from different species of *Scutellaria* to be unique in composition, and this is, in fact, evidenced by Nishikawa (see Figure 1). Furthermore, as evidenced by the Patent Office, "Sheu further teaches that the content of baicalin was dependent on the source of the plant material." Without having obtained the extract of Applicant's claims, one of skill in the art would not know from the teachings of the references that the extract of the quality of Applicant's rejected claims would be achievable from the source as taught by Applicant. If one did not know of the unique composition of the extract, it would not be obvious to one of skill in the art how to obtain it. Applicant respectfully submits that Claims 1-7 are thus free of the cited art. Reconsideration is respectfully requested.

Summary

In light of the above amendment, consideration of the subject patent application is respectfully requested. Any deficiency or overpayment should be charged or credited to Deposit Account No. 500282.

Respectfully submitted,



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